

K091632

510(k) Summary

3M ESPE

SEP - 3 2009

August 28, 2009

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

3M ESPE Dental Products
3M Center, Bldg. 275-2W-08
St. Paul, MN 55144-1000 USA

Establishment Registration Number

2110898

Contact Person

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Regulatory Affairs Specialist
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Device Name

SPK Sealant

Common Name

Dental Sealant, Pit and Fissure Sealant

Classification Name

Pit and Fissure Sealant and Conditioner

Regulation

21 CFR 872.3765

Class

II

Panel

Dental

Product Code

EBC

Predicate Devices

510(k)	Device Name
K992326	Clinpro Sealant, 3M ESPE Dental Products
K011491	Heliobond Clear Chroma, Ivoclar NA, Inc.
K062344	Grandio Seal, VOCO GmbH
K061997	Enamel Loc Sealant, Premier Dental Products Company
K073395	Glass Ionomer Protective Coating, 3M ESPE Dental Products

Description and Technology Equivalence:

SPK Sealant is moisture activated, light-cured, fluoride releasing pit and fissure sealant that can be applied with or without a phosphoric acid etch step. SPK Sealant is classified as a pit and fissure sealant because the device is composed of a methacrylate-based resin intended for sealing pits and fissures or other tooth surfaces to prevent cavities. Based on the indications for use, technological characteristics, and comparison of the predicate devices, the SPK Sealant has been shown to be safe and effective for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G60
Silver Spring, MD 20993-0002

Shari L. Myszka, R.Ph., Pharm.D.
Regulatory Affairs Specialist
3M Company
3M ESPE Dental Products
3M Center, Building 275-2W-08
St. Paul, Minnesota 55144-1000

SEP - 3 2009

Re: K091632
Trade/Device Name: SPK Sealant
Regulation Number: 21 CFR 872.3765
Regulation Name: Pit and Fissure Sealant and Conditioner
Regulatory Class: II
Product Code: EBC
Dated: August 28, 2009
Received: September 1, 2009

Dear Dr. Myszka:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Runner", followed by the letters "fac" in a smaller, less legible script.

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091632

Device Name: SPK Sealant

Indications for Use:

- Sealing pits and fissures, damaged enamel surfaces and exposed dentin surfaces of teeth to prevent caries
- Protective coating for tooth surfaces predisposed to caries or on early non-cavitated lesions (e.g. including use in tooth brush abrasion and root surfaces)
- Covering of caries predilection sites during orthodontic treatment

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Re: Mulvey for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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